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Docket No.: 1254-0326PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hideki SHIMADA et al.

Application No.: 10/594,771 | Confirmation No.: 6731

Filed: September 29, 2006 | Art Unit: 1632

For: DIAGNOSTIC KIT FOR SOLID CANCER AND MEDICAMENT FOR SOLID CANCER THERAPY | Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on September 29, 2006, attached hereto is an English Translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: JAN 17 2007

Respectfully submitted,

By Gerald M. Murphy, Jr. #48,501
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

Attachment(s)

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

HIRAKI, Yusuke
Kamiya-cho MT Bldg. 19F
3-20, Toranomon 4-chome
Minato-ku, Tokyo 105-0001
JAPON

Date of mailing (*day/month/year*) 26 October 2006 (26.10.2006)	
Applicant's or agent's file reference PH-2406-PCT	**IMPORTANT NOTIFICATION**
International application No. PCT/JP2005/006222	International filing date (*day/month/year*) 24 March 2005 (24.03.2005)
Applicant MEDICAL & BIOLOGICAL LABORATORIES CO., LTD. et al	

1. **Transmittal of the translation to the applicant.**

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference PH-2406-PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2005/006222	International filing date *(day/month/year)* 24 March 2005 (24.03.2005)	Priority date *(day/month/year)* 29 March 2004 (29.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 October 2006 (19.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference PH-2406-PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/006222	24.03.2005	29.03.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
MEDICAL BIOLOGICAL LABORATORIES CO., LTD.

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/006222

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/006222

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

   ☐ paid additional fees

   ☐ paid additional fees under protest

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

The polypeptides of SEQ ID NOs: 2, 4, 6, ... (omitted) ... 71, 73, and 75 do not have a shared chemical structure, and share only that they are human solid cancer antigen polypeptides. Nevertheless, human solid cancer antigen polypeptide is a publicly-known matter as described in the Published Japanese translation of PCT Patent Application 2000-511536. Thus, it cannot be stated that the inventions relating to polypeptides of SEQ ID NOs: 2, 4, 6, ... (omitted) ... 71, 73, and 75 described in claim 1 are a group of inventions so linked as to form a single general inventive concept, and it appears that the invention group consists of 36 inventions relating to 36 different polypeptides.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-20: the invention related to SEQ ID NO. 2

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/006222

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-20	YES
	Claims	1-3	NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations:

Document 1: DE 19818619 A1 (Metagen Gesellschaft fur Genomforschung mbH)
Document 2: WO 2003/032814 A2 (RAVEN BIOTECHNOLOGIES, INC.)

Claims 1-3

The inventions in claims 1-3 do not appear to possess novelty or involve an inventive step based on document 1 cited in the ISR. Polypeptide of SEQ ID NO: 2 and polynucleotide of SEQ ID NO:1 described in claim 1 are disclosed in SEQ. ID. 92 and 23 in document 1.

Claims 4-12

The ins in claims 4-12 appear to possess novelty based on document 1 cited in the ISR, but do not appear to involve an inventive step. Document 1 does not directly describe a kit for solid cancer diagnosis for detecting the expression of SEQ. 23 polypeptide described in document 1, but does describe the use of SEQ. 92 polynucleotide on the expression of usable polypeptides as a tool for the expression of an active substance the antibody of claim 20 and on bladder cancer in claim 28; when the sequence of a detection target antigen polypeptide is specified, the use of a probe, primer, or similar item formed from antigen, polypeptide, and/or polynucleotide, as a kit for the detection of the expression of a detection target antigen polypeptide is merely a commonly used technique for a person skilled in the art. In addition, because SEQ. 23 polypeptide as shown in the table on page 27 on document 1 is expressed in tissues other than bladder cancer, use of this kit in the detection of cancers in other tissues could be easily conceived of by a person skilled in the art.

Claims 13-20

The inventions in claims 13-20 appear to possess novelty based on documents 1 and 2 cited in the ISR but do not appear to involve an inventive step. Document 1 does not directly describe a medicine for solid cancer prevention or therapy that includes steps for the suppression of the function or expression of SEQ. 23 polypeptide, but does describe the antibody in claim 20. When cancer-specific polypeptide sequences are specified, the use of said antibody as a medicine, and the execution of inhibition of transcription and translation of genes encoding said polypeptide are merely commonly used techniques for a person skilled in the art. In addition, making a medicine of a complex that includes the antibody of document 1 rather than a complex disclosed in document 2 wherein an antibody and a therapeutic agent are combined could be easily conceived of by a person skilled in the art.